ATMOS
MedizinTechnik

English

Operating instructions

Atmoport N

CE 0124

312.0400.B
312.0405.B

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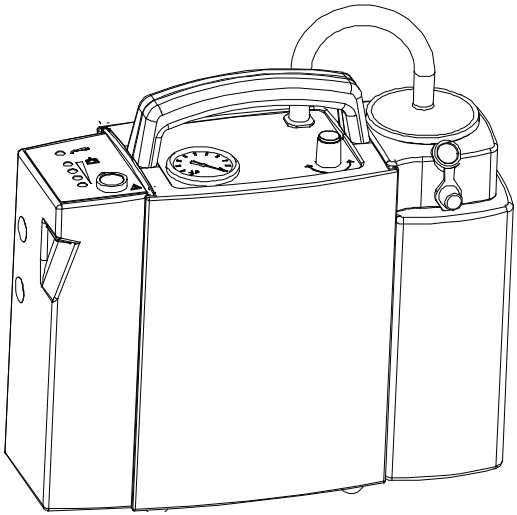

ATTENTION:

Prior to starting the **Atmoport N**, *please read these operating instructions carefully and keep them near the unit for later reference.*

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2.1 Dispatch

The **Atmoport N** was subjected to a thorough quality control before shipment. Carefully inspect the device immediately for any signs of damage and check the contents of the carton against the delivery note. In case of transport damages, please contact immediately the competent sender and carrier.
Return shipment of the unit to the sender (e.g. for repair) is only to be effected in an undamaged shipping carton.

2.2 Explanation of symbols

Symbol "Caution: pay attention to operating instructions" acc. to DIN 30600 1008, IEC 348
This symbol accentuates information relating to safety and refers to important details when applying the unit.

ON/OFF switch

Important information on use of this unit.

Protection class II

Degree of protection: type BF (body floating)

Short-time operation

Charging of battery

Connection to bacterial filter

Charge battery

External supply

On / Off

Contains Phthalates: Bis(2-erhylhexyl)phtalate (DEHP)
The fingertip consists of PVC. Small amounts of the plasticiser DEHP may be released from the hose.

2.3 For your safety

The safety standard of the **Atmoport N** corresponds with recognized medical technical regulations and the directions of the law relating to medical products.

The **Atmoport N** has been designed acc. to EC-directions on medical products 93/42/EEC Annex IX and has been classified as suction unit of group IIa. The unit is marked with the sign CE 0124. The declaration of conformity will be provided on request on indicating the serial number of the unit.

The **Atmoport N** fully complies with the electromagnetic immmunity requirements of standard IEC 601-1-2/EN 60601-1-2 "Electromagnetic compatibility - Medical Electrical Equipment". Electromagnetic interferences and interactions have thus been reduced to the minimum.

Only persons instructed in medical use may apply the **Atmoport N** to patients.

Before connecting the charging power pack to the power supply, check whether the voltage stated on the data plate corresponds with the inbuilding voltage.

Never connect the unit to defective power sockets or extension cables.

Avoid moisture on plug and switches.

The unit may not be started:
- if cables or the charging power pack are defective,
- if it has been dropped down before,
- if obvious defects might restrict safe operation.

In any case, have the unit checked by the service staff.

Opening the interior of the unit for service work may only be effected by authorized service personal or technical specialists. Before opening the unit, dis-connect the charging power pack from the device.

Only use original accessories and spare parts.

This product is not re-sterilisable. Repeated reuse of components which are marked with a ② is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.

The **Atmoport N** may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.

2.0 General

The **Atmoport N** has been designed for aspirating body fluids in medical ranges.
Never remove explosive gases and inflammable or corrosive fluids.

Disconnect the charging power pack:
- before cleaning the unit,
- before the collection jar is evacuated.

Never pull at the cable of the charging power pack !

The unit may not be operated in splash water range, in high ambient temperatures and in locations where there is a danger of explosion (zones M and G).

Never plunge the unit into water, not even when it is switched off.

Only operate the unit in upright position and on a firm, level surface.

Send unit only in padded shipping carton !

When operating the unit at ambient temperatures out-side the stated temperate range, the performance and operating period are reduced.

Please note:
A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.

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The fingertip contains phthalates which are categorised as toxic for r production in category 2. This applies particularly to children, pregnant and breastfeeding women. As a preventive measure we recommend avoiding direct contact with the skin. The residual risk, which may arise through possible ex posure and due to the short term application, can be valued as insignificant compared to the benefit of the product.

2.4 Intended use

The **Atmoport N** is used in the medical range for removing secretion and body fluids.

Special medical ranges for applying this unit are:

- first aid posts, ambulance stations, wards, old people's and nursing homes;
- ambulant and home care of old people for spontaneous suction of mucus from the respiratory tract;
- military infirmaries, field hospitals.

The suction hose must never come into direct contact with the application site. A suction catheter must always be connected to the hose. Suction catheter and connector, see *accessories*.

The **Atmoport N** may ***not*** be used:

– for drainages in low vacuum range (e.g. thoracic drainages) and for suction procedures outside medical ranges;

– for the suction of inflammable, corrosive or explosive fluids/ gases.

At regular intervals, the device must be checked for proper operation and safety defects, e.g. charging set, plug contacts, collection jar, housing, and so on.

ATMOS does not assume responsibility for the unit, for users, objects and affected persons if the **Atmoport N** is used without observing the instructions in this manual.

2.5 Technical specifications

Air flow rate of pump	36 ± 2 l/min
Max. vacuum at sea level	-79 kPa* (-790 mbar; -593 mmHg)
Vacuum readout	-1...0 bar (± 25 mbar) (mm Hg; kPa)*
Additional air regulation	mechanical regulating valve
Collection jar	1 l plastic
Suction hose	ø 6 mm, 1.30 m length
Voltage ranges (charging power pack)	100 V~ to 240 V~ 50/60 Hzwithout switching
Low voltage connection (charging power pack)	12 V DC
Car connecting cable	12 V car mains
Current input (max.)	3.8 A
Power consumption	46 W
Battery, rechargeable	12 V, 2400 mAh, NiCd
Charging time of the battery, rechargeable	approx. 2 hours with 12 V DC
Operation mode	Interrupted useCooling period: approx. 20 min.
Operating time with battery	approx. 45 min.
Operating time with mains supply or low voltage connection	approx. 60 min.
Fuse (charging power pack)	slow-blow 1 A/H for 250 V
Protective earth conductor resistance	—
Earth leakage current	—
Enclosure leakage current	N.C. < 0.1 mA
Patient leakage current	—
Heat emission	46 J/s
Noise level	54.9 dB (A) @ 1m (acc. to ISO 7779)
Ambient conditionsTransport/storage	-30...+45°C20...80 % humidity, non-condensingair pressure 700...1060 hPa
Operation	-5...+40°C20...80 % humidity, non-condensingair pressure 700...1060 hPa
Dimensions HxBxT	262 x288 x 106 mm
Weight	approx. 3.8 kg
Protection class (EN 60601-1)	II
Degree of protection	Type BF
Protection category	IPX 1 (drop water protection)
Protection class	I
Classification acc. to Annex IXEEC directions 93/42/EEC	IIa
CE marking	CE 0124
Rules applied	EN 60601-1: 1990 +A1: 1993 + A2: 1995EN ISO 10079-1: 11/1996EN 60601-1-2: 1993 (EMV / EMC) EN 30993: 1994
UMDNS-Code	15-016
Reference-No.	312.0400.0
CanadianClassification	
Device Group	Ear, Nose and ThroatPNC
PNC	77QBW
Risk class	2
Description	ASPIRATOR, TRACHEAL

*1 bar @ 750,06 mm Hg @ 1000 hPa / depends on daily atmospheric pressure

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3.0 Connecting, starting and operating the Atmoport N

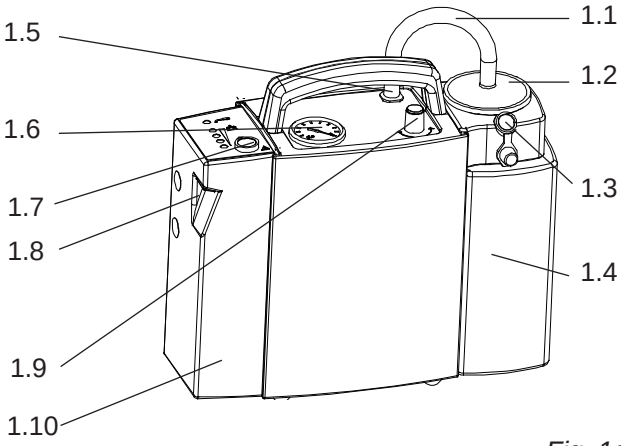


Fig. 1a **Atmoport N**

1.1 Connecting hose
1.2 Bacterial filter
1.3 Attachment (for suction hose)
1.4 Collection jar
1.5 Hose attachment (on the unit)
1.6 Vacuumgauge
1.7 ON/OFF switch
1.8 Connection socket for power pack
1.9 Vacuum regulator
1.10 Battery pack

3.1 Functioning

The **Atmoport N** is a very handy small suction unit. It is driven by an electromotive, maintenance-free diaphragm-type pump. During operation, the pump generates a vacuum within the tube system and the collection jar, thus sucking off secretions or fluids (e.g. by means of a suction catheter). The fluid is gathered in the collection jar. A mechanical overflow safety (on the inner part of the collection jar lid) avoids penetration of secretion into the pump head. The final vacuum and, following, the air-flow rate can be adjusted by means of the fine control and the vacuumgauge. The unit is equipped with a re-chargeable batteries (accumulator). Integrated micro-processor-based technology assures safe charging of the battery; over-charging is thus impossible. An overtemperature stop controlled by electronics avoids overheating of the unit. A bacterial filter integrated in the lid of the collection jar prevents bacteria and liquid from penetrating into the pump.

3.0 Connecting, starting and operating the Atmoport N

3.2 Starting the unit

In order to fully charge the battery, connect the charging power pack to the mains supply or the car connecting cable to the cigarette lighter of the car and join it with the socket (1.8, Fig. 1) on the **Atmoport N**.
Always connect the suction unit to the charging power pack when the unit was used in order to have a 100% fully charged unit available when required. The car connecting cable supplied with the unit is used for operating the unit and for charging the battery. The charging procedure takes 1-2 hours when the battery is empty.

Operation in car:
If no mains connection is possible inside the house, operation of the unit is possible employing the 12 volt car battery via a car connecting lead. To do this, plug the car connecting lead into the low-voltage junction box of the unit and the universal low-voltage plug into the cigarette lighter socket of the car.

Line voltage operation:
Connect the charging power pack to the mains (Fig. 1.11) and the low voltage attachment (Fig. 1.12) to the socket on the **Atmoport N** (Fig. 1.8). Pay attention to correct voltage values.

Use the unit only with **bacterial filter** and **overflow safety**.

If the battery is discharged, the unit may also be operated with connected charging power pack. In this case, however, the battery is not being charged.

The unit may be used in upright position only. As soon as the collection jar contains liquid the unit must be placed into upright position. The inserted overflow safety can work in upright position only, whether the unit is being used or not.

The unit may be stored away or transported in horizontal position only when the collection jar has been completely emptied.

Before transporting the unit, make sure that the cover is firmly closed.

Operate the unit with 12 volt car voltage only, using the original connecting lead (not for use with 24 volt car voltage).

3.0 Connecting, starting and operating the Atmoport N

3.3 Operation

If the **Atmoport N** is used e.g. for suction of mucus from the upper respiratory tract, proceed as follows:

- Adjust your desired maximum vacuum by closing the suction hose opening (fig. 3.2) with the finger ; the vacuum is then generated. Open the regulating valve (fig. 1.9) until the vacuumgauge shows the desired vacuum value (fig. 2).
- Choose a suction catheter of the right size (e.g. Unoplast catheters, fig. 3.4, which are available from ATMOS in 3 different sizes) or a suction instrument which is only available from specialized dealers.
- Join the suction tube (fig. 3.2) and the suction catheter (fig. 3.4) by means of the fingertip (not included in delivery, please order seperately REF 000.0347.0) (fig. 3.3).
- Then, lead in the catheter in the same way as shown by your hospital staff and start the suction procedure. Never start suction procedures without having been instructed by hospital staff.

Attention: Suction procedures in the respiratory tract may only be implemented after appropriate instruction by hospital or special staff.

- Control the suction procedure with the finger tip.
- Rinse suction catheter and suction tube with clean water after every suction procedure.

Make sure that the collection jar is evacuated in time. As soon as the jar is half-filled, it must be emptied (this principle proves right in all application ranges).

When the maximum level is exceeded, the overflow safety reacts and suction is stopped. Empty the jar as described in section 4.1.

If secretion has penetrated the pump, the Atmoport N has to be maintained by a service technician.

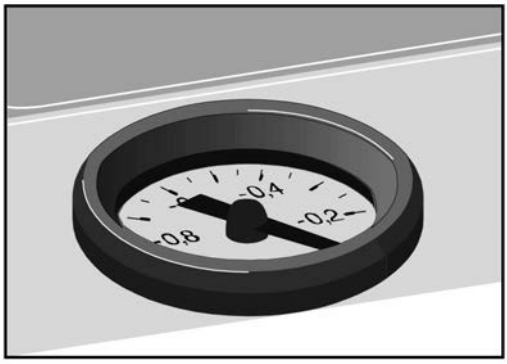


Fig. 2 Vacuumgauge

3.0 Connecting, starting and operating the Atmoport N

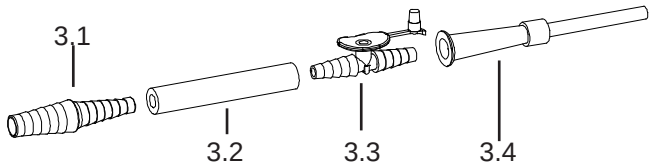
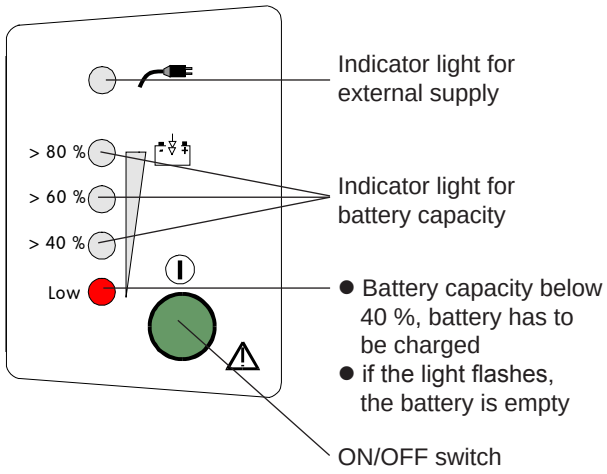


Fig. 3 Finger tip

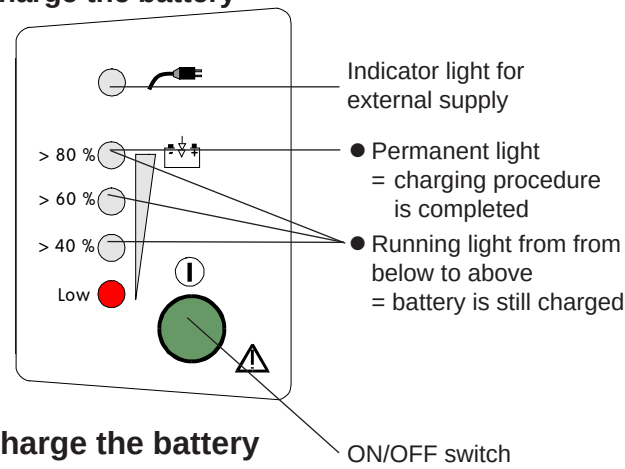
AUXILIARY AIR VENT OPEN = suction procedure is interrupted (e.g. when leading in the catheter)
AUXILIARY AIR VENT CLOSED WITH THE FINGER = suction

3.4 Operating modes

1. Suction


> 80 %
> 60 %
> 40 %
Low
Indicator light for external supply
Indicator light for battery capacity
● Battery capacity below 40 %, battery has to be charged
● if the light flashes, the battery is empty
ON/OFF switch

2. Charge the battery


Indicator light for external supply
> 80 %
> 60 %
> 40 %
Low
● Permanent light = charging procedure is completed
● Running light from from below to above = battery is still charged
ON/OFF switch

3.5 Charge the battery

New processor-controlled charging electronics de-termine, between charging current impulses, the energy reserve and condition and adjust charging current parameters acc. to the respective charging characteristic. Complete charging is thus achieved and charging procedure is automatically finished and indicated. The charging period comes to approx. 2 hours.

The battery can be charged by mains or 12 V low voltage supply.

When starting the unit for the first time or after a long period of time when the unit has not been used we recommend starting the charging procedure once again. To do so, remove the power cord or the 12 V low voltage attachment from the unit and insert it again.

Correct handling of the rechargeable batteries prolongs their maximum service life.

Rechargeable batteries are wearing parts and therefore excluded from the 2 years' product liability!

3.6 Electrical connections

– For mains operation: Connection via the charging power pack.
  Low voltage connection via the low voltage socket 12 Volt DC. Attention, only use cable intended for this purpose.

– Operation in car via the 12 V connection cable joined with the car mains or the cigarette lighter.

Operation of the suction pump is possible with both kinds of connection.

Attention: Double-pole and quadripolar connector plugs can be used. Please pay attention when using the double-pole connector it must be plugged in centrally in the charging socket.

4.0 Cleaning and servicing

4.1 Evacuating the collection jar

– Take off the connection hoses (suction hose and unit connection hose) from lid.

– Withdraw collection jar with lid from the guides upwards.

– Open the collection jar lid by lifting.

– You can then empty the collection jar.

4.2 Cleaning the collection jar parts

Before emptying and cleaning the collection jar, remove the electrical connections from the unit.

Collection jar and collection jar lid can be rinsed under running water or cleaned in an automatic cleaning device.

4.3 Cleaning and disinfection

The unit can be wiped with a moist (not wet) cloth.
Basically, all parts which come into contact with secretion must be cleaned and disinfected after each suction procedure. Dependent on the application con-ditions, the hospital staff may determine other cleaning- and disinfecting- agents and cycles. These parts may also be immersed in commercial disinfectants (see next page).

Attention: The lid parts and silicone hoses might get dyed by some disinfectants; a fact which does not take effect on the attributes of the materials. The silicone parts and collection jar parts may also be boiled (for more that 10 min.).

4.0 Cleaning and servicing

ATMOS recommends following disinfectants for instruments and surfaces.
ATMOS guarantees unrestricted use of the unit only if the instructions by the respective manufacturer are observed.

Recommended instrument disinfectans:

Disinfectant	Ingredients (per 100 g)	Manufacturer
neodisher MediClean forte (Application concentrate)	non-ionic tensides < 5 g NTA (nitrilotriacetic acid) 5-15 g enzymes, preservative agent	Dr. Weigert, Hamburg
Gigasept FF new (Application concentrate)	succinic acid dialdehyde 11,0 g dimethoxy tetrahydrofurane 3,0 g corrosion inhibitors	Schülke & Mayr, Norderstedt

Recommended surface disinfectans:

Disinfectant	Ingredients (per 100 g)	Manufacturer
Dismozon pur (Application concentrate)	magnesium monoperoxyphthalate hexahydrate 80 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	alkyl-dimethyl-benzyl-ammonium chloride < 1 g dialkyl-dimethyl-ammonium chloride	Metasys, Rum (Österreich)

If using aldehyde-containing or amine-containing disinfectants at the same object, this may result in discolourations.

4.0 Cleaning and servicing

4.4 Bacterial filter

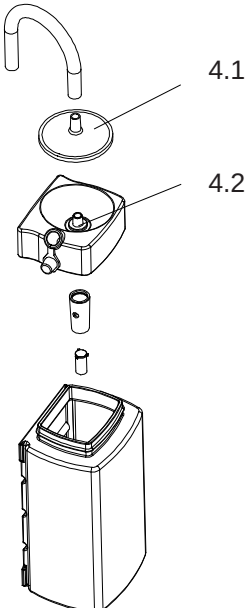


Fig. 4 Bacterial filter
4.1 Bacterial filter
4.2 Filter connection

This suction unit may be used with bacterial filter only !

4.4.1 General

There is a bacterial filter (Fig. 4.1) at the lid of the **Atmoport N** which
a) protects the interior of the unit against contamination,
b) stops the flow of liquids due to its hydrophobic features.

Together with the mechanical overflow safety this filter prevents sucking in of secretion into the interior of the unit, and, due to this, failure of the unit

Attention! The bacterial filter is a consumable and is neither autoclavable nor can it be disinfected.
For hygienic reasons an exchange of the filter is recommended at least every 7 days, but at the latest when the device is used for an other patient.

4.4.2 Filter change

Removing the filter:
Remove the filter from the unit and take off the silicone hose. Dispose of the filter.

Installing the filter:
Connect the new filter to the silicone hose (after the silicone hose has been cleaned and disinfected). Reconnect filter to connection 4.2.

4.4 Bacterial filter (contin.)

Recommendation:

- In private use, the filter should be replaced every 2 to 3 weeks. If suction performance decreases, the filter has to be changed earlier !
- In hospital use, the filter must be replaced every week.
- If, with the unit switched on and the suction hose open, the vacuum display changes to a value below -0.3 bar, the filter is blocked and must be replaced.

☞ **Attention:**
Please take care that there are always sufficient spare filters available.
(Filter, Art.No. 312.0439.0)

☞ Make sure that the collection jar is not filled more than half, in order to prevent secretion to get into contact with the filter. In this way, you can carry out many suction procedures with the filter.

☞ Pay attention to correct hose connections of suction system and to correct function of overflow safety.

Information on cleaning

		afetr each patient	after suction procedure	1x per day	1x per week	after 4 weeks
Secretion canister	cleaning	x	x			
	disinfection	x		x		
Secretion canister lid	cleaning	x	x			
	disinfection	x		x		
Housing	cleaning / disinfection	x			x	
Bacterial filter				exchange		
Fingertip				exchange		
Suction hose	cleaning				x	
	disinfection	x	x	x		exchange
Connecting hose	disinfection				x	exchange
Hose connector						exchange

The **Atmoport N** was subjected to a thorough quality control before shipment. If there is, nevertheless, some malfunction, you possibly might solve this problem yourselves if you observe the following instructions:

Problem	*Possible causes*	*Remedy*
● Unit does not start	– Loose power plug and discharged battery	– Check connection to supply socket
	– No power voltage and battery is discharged	– Check inbuilding fuse – Check whether power plug on the unit is loose
	– Defective fuse (charging power pack)	– Replace fuse
	– Discharged battery	– Charge battery
● Insufficient performance	– Leakages within the hose system or in collection jar lid	– Check collection jar lid and hose system
	– Clogged filter (vacuumgauge indicates vacuum)	– Clean or replace filter
	– Discharged battery	– Charge battery
● No suction	– Float of overflow safety closes the collection jar inlet	– Check filling level of collection jar; evacuate jar, if necessary; clean overflow safety and check free movement of the float
	– Blocked filter	– Replace filter in collection jar lid and check correct hose connections
	– Secretion or blood has been sucked in and valve plates of the pump are contaminated	– Unit has to be returned for repair
● Indicators flash irregularly	– Electronics are defective	– Unit has to be returned for repair

6.0 Spare parts and accessories

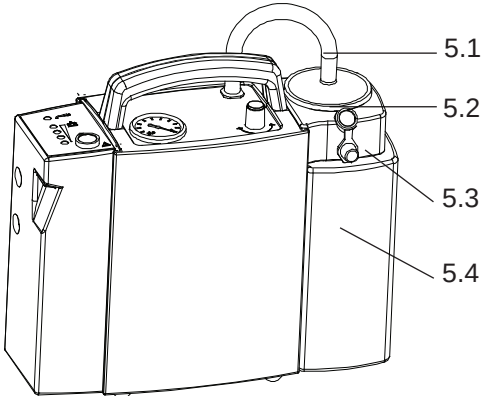


Fig. 5a **Atmoport N**

5.1 Silicone connection hose
5.2 Bacterial filter
5.3 Collection jar lid
5.4 Collection jar
5.5 Hose connector
5.6 Suction hose
5.7 Finger tip
5.8 Suction catheter

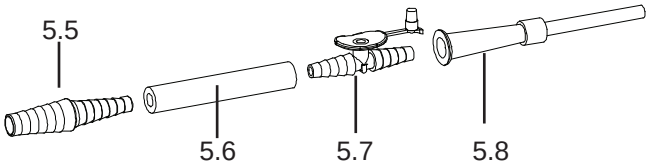


Fig. 5b Finger tip

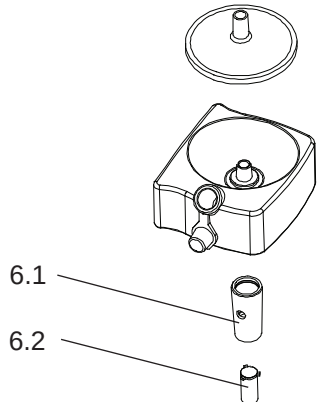


Fig. 6 Collection jar lid

6.1 Float sleeve
6.2 Float

6.0 Spare parts and accessories

Spare parts for **Atmoport N:**

Fig.	*Description*	*Article-No.*
5.1	Connection hose, silicone, ø 6mm	320.0047.0
5.2	Bacterial filter	312.0439.0
5.3	Collection jar lid	312.0625.0
5.4	Collection jar 1l	312.0626.0
5.5	Hose connector 7 - 10	000.0239.0
5.5	or - hose connector 9 - 13	000.0268.0
5.6	Suction hose, ø 6mm	000.0013.0
5.7	Hose connector (finger tip)	000.0347.0
6.1	Float sleeve	312.0442.0
6.2	Float	320.0015.0
no fig.	Car connecting cable (12 V car mains)	312.0436.0
no fig.	Battery pack NEW	312.0425.0
no fig.	EXCHANGE battery pack (reprocessed in factory)	312.0425.1
no fig.	Shoulder bag, orange	312.0450.0
no fig.	Support for use in car	312.0410.0
no fig.	Operating instructions	312.0400.B

Attention:
The manufacturer considers himself responsible for safe operation of the unit only if original accessories and spare parts are used.

Accessories for **Atmoport N:**

Fig.	*Description*	*Article-No.*
5.8	Unoplast suction catheters "Optimal", straight, central opening, 2 small lateral openings, length: 50 cm, each packed separately and sterile in packing lots of 100 pcs.	
	Size: Charrière 12	000.0294.0
	Charrière 14	000.0295.0
	Charrière 16	000.0296.0
no fig.	Rinsing jar 250 ml	000.0504.0
no fig.	Lid for rinsing jar	000.0504.1
no fig.	Charging power pack	312.0449.0

7.0 Maintenance and repair

7.1 Maintenance and regular checks

The **Atmoport N** is equipped with an maintenance-free diaphragm-type pump. Regular maintenance work is not necessary. The battery pack contains NiCd batteries. Depending on the frequency of charging and dis-charging procedures, the batteries will abrade. The remaining capacity of the batteries should be checked every 2 - 3 months (7.1.1).

The **Atmoport N** may only be opened and repaired by persons explicitly authorized by ATMOS. Technical and hygienic pre-cautionary measures have to be observed.

The manufacturer rejects liability for performance of the unit if it has been improperly repaired or if no original spare parts have been used. If the unit is opened during warranty period warranty claims will no longer be accepted by ATMOS.

A service manual containing detailed circuit diagrams and spare parts lists is available from service organizations authorized by ATMOS.

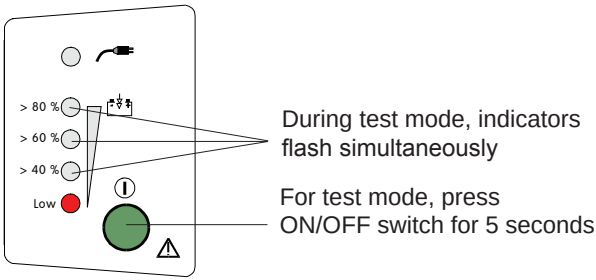
The cardboard packing can completely be recycled or may be returned to the respective ATMOS representative in your country.

7.1.1 Battery handling

- Prior to first use, the battery must be fully charged!
- Total discharge may destroy the battery. Therefore, please fully recharge the batteries of the Atmoport N every 3 months, even if the device is not used.
- Battery-run devices should only be stored when they are fully charged.
- If the device was not in operation for a long period of time, the full capacity of the battery can only be achieved when 4 complete recharging and discharging cycles have been completed.
- Used batteries should be replaced immediately by the customer service. The mains operation of the device with used batteries can destroy the charging electronics respectively excessive power consumption of the device may result in a spontaneous cut-off.
- Heat destroys the batteries. Therefore, please prevent them from direct solar radiation and keep them away from radiators. The perfect storage temperature is between 8 – 15°C.
- The battery should be exchanged by the service department if the available capacity (operating time) is less than 80 % compared with a new battery.
- Conditional of manufacturing batteries are run-down after approx. 800-900 charging cycles.

7.1.2 Checking the battery (procedure will take approx. 4 hours)

1. Connect external power supply.
2. Press ON/OFF button for about 5 seconds.
3. Testing process starts; the three green LED's flash si-multaneously. With this mode, the battery capacity can be recognized.
4. First, the battery is charged.
5. Then, the battery operation (unit is running) is auto-matically switched on. Thus, the battery is completely discharged (will take approx. 45 min.).
6. The unit switches off when the battery is discharged.
7. Then, the battery is again charged (will take approx. 2 hours).



7.1.3 Test evaluation

The test mode is completed when the indication > 80 % or a value below lights up.

Analysis (indication lights up):

> 80 % Battery in very good condition.
Almost full capacity.

> 60 % Battery capacity still good.

> 40 % Battery has lost more than half of its charging capacity and should be replaced.

> Low Battery must be replaced soonest possible.

Change of complete battery pack:
To do so, remove the two cover caps on the battery pack and loose the two screw connections. Then, the battery pack can be lifted out of the guide. For replacement, ATMOS offers new battery packs (312.0425.0) or exchange packs (312.0425.1,reprocessed in factory and more fa-vourable in price).

Change of batteries inside the battery pack:
Replacement of the batteries inside the battery pack may only be effected by an authorized service technician.

8.0 Disposal

At the end of durability, dispose of the components of the **Atmoport N**, observing the applicable waste-control regulations. In doing so, make sure that the materials are carefully separated.

The **Atmoport N** does not comprise any hazardous materials. The material of the housing can be completely recycled.
Also dispose of the batteries according to the applicable waste-control regulations.

Cleaning and servicing plan for ATMOS LC 16, Atmolit, ATMOPORT

start date:: **name of the item:** **serial number:**

day	cleaning secretion container	cleaning container lid	cleaning of the housing	exchange of bacterial filter	exchange of fingertip	exchange of suction hose, 1.3 m	exchange of connecting hose	cleaning/exchange performed	
								name	signature
	daily, respectively after each use	daily, respectively after each use	daily, respectively after each use	exchange*	exchange*	exchange*	exchange*		
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* Before first time operation of a brand new device, respectively a reprocessed device, an exchange is unnecessary!

Special notes:
Before operating the suction device, the user has to make sure that the device functions and is in good order and condition. The user has to observe the instructions in the operating manual as well as all other safety-related and maintenance information enclosed.

For cleaning and disinfection only agents which are recommended by the manufacturer, may be used.
Only sterile, single-use suction catheters may be used for suctioning. They have to be exchanged before each suction process. During use utmost attention to hygiene (e.g. disinfection of hands, wearing single-use gloves) is indispensable. After each use the secretion container and the hose must be rinsed thoroughly with water. During storage the contamination of the device and other products must be avoided. The intervals stated in the list are non-binding guide values. Depending on the use shorter intervals may be necessary.

For each patient a new or a reprocessed suction device must be used. Otherwise there is high and acute danger of infection for the patient, the user and any third person!

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Important notes

General information

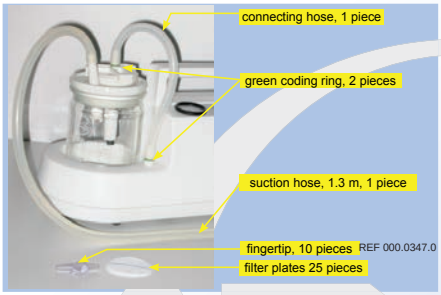
The way the suction device is used determines its reliability and safety. These hygiene measures are indispensable for protecting the patient and the user and for maintaining a safe and reliable suction device.

These measures do not replace a reprocessing, performed by the manufacturer or by any certified ATMOS partner before re-using the device on a new patient.

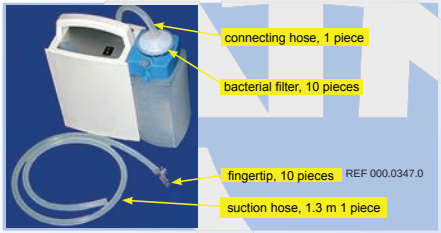
This cleaning and servicing plan as well as the relevant notes result from many years of experience. Depending on the use and the user's experience shorter intervals may be necessary.

ATMOS recommends the following sets of consumables:

320.0125.0 für LC 16, Atmolit 16N, Atmolit 26


connecting hose, 1 piece
green coding ring, 2 pieces
suction hose, 1.3 m, 1 piece
fingertip, 10 pieces REF 000.0347.0
filter plates 25 pieces

312.0615.5 für ATMOPORT, ATMOPORT S, ATMOPORT N



suction catheter, length: 50 cm, 100 pieces

☞ Disconnect the mains plug from the socket before commencing with cleaning and disinfection!

☞ Please observe the notes in the operating instructions, especially regarding the recommended agents.

Cleaning of the secretion container

Please empty the secretion container after each use, rinse it thoroughly with warm water and clean it with washing-up liquid. Tenacious contaminations can be removed with a standard bottle brush.

Cleaning of the container lid

The bacterial filter must be removed before cleaning, please use single-use gloves or tweezers. Please demount the container lid after each use and rinse it thoroughly. The lid must be absolutely dry before reuse. Please pay attention to a correct function of the overflow safety when mounting the lid.

Bacterial filter

The bacterial filter prevents penetration of micro organisms and secretion into the device, respectively blowing out from it and is therefore a protection for the user and the device. For hygienic reasons a weekly exchange is recommended. If the maximum vacuum is adjusted, the suction hose is open and the vacuum gauge shows a basic vacuum of > -0.3 bar, then the bacterial filter must be exchanged immediately. In case of contamination the filter must also be replaced. In order to increase the service life of bacterial filters, it is recommended to empty the secretion container when it is half-full. Always use the original ATMOS bacterial filter.

☞ Never use the suction device without bacterial filter!

Hose connection/fingertip

The fingertip connects the suction hose to the suction catheter. The fingertip is in continuous contact with secretion and is difficult to clean, therefore we recommend an exchange every 2 or 3 days.

Suction Hose

The suction hose conducts the secretion from the suction catheter to the container. In order to prevent secretion from drying, the hose must be thoroughly rinsed with clear water after each use. The water can be sucked into the secretion container. Please fill the secretion container only half. Frequent cleaning and disinfection may discolour and embrittle the hose. Therefore, a monthly exchange of the suction hose is recommended.

Connecting hose

This hose is the connection between secretion container and the vacuum pump. For hygienic reasons a monthly exchange of the hose is recommended.

Coding rings

On the LC 16, Atmolit 26 and Atmolit 16 N, the green coding rings mark the positions where the connecting hose is connected to the container lid respectively bacterial filter housing and the nipple at the device.

Cleaning of the device (housing)

When the device is contaminated but at least once per week the housing must be wiped off with a moist (but not wet) cloth. A weekly disinfection is recommended.

☞ Never irrigate the device with water and never emerge it into any liquid.

Cleaning/disinfection

To improve the cleaning effect, standard washing-up liquid can be added to the warm water. In the case of tenacious contamination the parts should be steeped in water for a length of time or they may be removed with a soft brush or cloth. After thorough cleaning, container, fingertip and hoses can be disinfected with a disinfection agent (see operating instructions).

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- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

10.1 Guidelines and Manufacturer´s Declaration - Emissions

The Atmoport N is intended for use in the electromagnetic environment specified below. The customer or user of the Atmoport N should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Atmoport N uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in near-by electronic equipment.
RF Emissions CISPR 11	Class B	The Atmoport N is suitable for use in all esta-blishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Inapplicable	
Flicker IEC 61000-3-3	Inapplicable	

The device may not be used directly next to other devices or piled up with other devices.
If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

10.2 Guidelines and Manufacturer´s Declaration - Immunity

The Atmoport N is intended for use in the electromagnetic environment specified below. The customer or user of the Atmoport N should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains Inapplicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 1 kV Common	± 2 kV Differential ± 1 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	Inapplicable	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environ- ment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Atmoport N demands continued function even in case of interruptions of the energy supply, it is recommended to supply the Atmoport N from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

10.3 Guidelines and Manufacturer´s Declaration - Immunity

The Atmoport N is intended for use in the electromagnetic environment specified below. The customer or user of the Atmoport N should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the Atmoport N incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** $d = (3,5 / V_1) * \sqrt{(P)}$ $d = (3,5 / E_1) * \sqrt{(P)}$ 80-800 MHz $d = (7 / E_1) * \sqrt{(P)}$ 0,8-2,5 GHz where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (*a*) survey, should be less than the compliance level (*b*). Interference may occur in the vicinity of equipment containing following symbol.
Conducted RF IEC 61000-4-6	$V_1 = 3\ V_{eff}$ 150 kHz to 80 MHz	3 V	
Radiated RF IEC 61000-4-3	$E_1 = 3$ V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1	With 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2	These guidelines might not be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.
a	The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the Atmoport N is used exceeds the above compliance level, the Atmoport N is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.
b	Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

10.4 Recommended separations between portable and mobile RF Communications equipment and the Atmoport N

The Atmoport N is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Atmoport N can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the Atmoport N as stated below, according to the maximum output power of the communications equipment.

	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter **W**	**150 kHz bis 80 MHz** **d =** [3,5 / 3] √**P**	**80 MHz bis 800 MHz** **d =** [3,5 / 3] √**P**	**800 MHz bis 2,5 GHz** **d =** [7,0 / 3] √**P**
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.4
10	3.69	3.69	7.38
100	11.66	11.66	23.32

For transmitters for which the maximum nominal output isn´t indicated in the above table, the recommended separation distance *d* in meters (m) can be determined using the equation belonging to the respective column whereas *P* is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer´s specification.

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines are not applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE CE

ATMOS MedizinTechnik

Wir / We / Nous

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erklären in alleiniger Verantwortung, dass das Medizinprodukt /
declare under our sole responsibility that the medical device /
déclarons sous notre pleine et entière responsabilité que le produit médical

Klassifizierung / Classification / Classification : II a

Name / name / Nom:	ATMOS **Atmoport N** ..... **REF 312.0400.0**
Varianten / models / Variante:	ATMOS **Atmoport N** ..... **REF 312.0401.0**

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht. /
meets all applicable requirements of the Directive 93/42/EEC /
répond à toutes les exigences applicables de la directive 93/42/CEE

Name, Adresse und Kennnummer der Benannten Stelle:
Name, address and identification number of Notified Body:
Nom, Adresse et Numéro d'identification de l'organisme notifié :

CE 0124

DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart

Konformitätsbewertungsverfahren:	Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007 /
Conformity assessment procedure:	Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 /
Procédé d'évaluation de conformité :	Directive 93/42/CEE, Annexe II du Conseil sur les produits médicaux, passée en commission le 14 juin 1993, dernière modification le 5 septembre 2007.

Gültig bis auf weitere Änderungen am Produkt bis 29. März 2015.
Valid till further changes on the product until March 29th 2015.
Valide jusqu'à modification du produit, jusqu'au 29 mars 2015.

Lenzkirch, den 28.03.2012
Place and date of issue

Frank Greiser
Geschäftsführer / Managing Director / Directeur

i.V. Steffi Focke
Sicherheitsbeauftragter / Safety Inspector / Chargée de la Sécurité

Qd 148-9_CE0124_IIa

ATMOS General terms and conditions

1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved.Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coin-cidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compen-sation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;

b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.

c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;

d. We accept no responsibility for damage defects caused by

- operational wear and tear;
- incorrect installation or incorrect or insufficient maintenance;
- incorrect operation of the product (in contradiction to the handbook delivered with the product); - improper use or operating faults; - inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation; - using accessories and/or replacement parts which are not explicitly approved;
- incorrect assembly and/or initial operation by the client or third parties; - the client's negligence in handling the product; - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.
- accidents, acts of God, especially lightening, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for tthat case. This also applies in the case of our culpable infringement of substantial contractual duties The indispensable conditions of German Liability Law remain unaffected thereby.
- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods repre-sents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income form such use is balanced against the client's arrears, after deducting appropriate utilisation costs.The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby.We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law.Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, September 2008
ATMOS MedizinTechnik GmbH & Co. KG
79853 Lenzkirch/Germany

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